

Remarks

The February 11, 2004 Official Action has been carefully considered. In view of the amendments presented herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset it is noted that a shortened response period of three months was set in the February 11, 2004 Official Action. Accordingly, the initial response period is due to expire May 11, 2004. This amendment and request for reconsideration is being filed before the expiration of the initial response period.

As another preliminary matter, the examiner's attention is called to the fact that an information disclosure statement and a supplemental information disclosure statement, both in compliance with 37 C.F.R. §1.97 and 1.98, were filed March 23, 2001 and February 5, 2004, respectively, in the present application. It is respectfully requested that, in accordance with the guidelines of §609 of the Manual of Patent Examining Procedure, the examiner consider and make of record in this application the prior art references listed in the Forms PTO-1449 which were submitted with the aforementioned information disclosure statements.

Regarding the requirement for restriction set forth in the Official Action dated April 1, 2003, this requirement has been modified, in that the claims of Groups XIII-XXX are now considered one group, and otherwise made final.

Applicants wish to make clear once again that the election made in response to the aforementioned restriction requirement is without prejudice to applicant's right to file one or more divisional applications, as provided in 35 U.S.C. §121, directed to the subject matter held finally withdrawn from consideration in this application.

In the February 11, 2004 Official Action, the examiner objects to claim 50 because it refers to a non-elected claim. This objection is overcome in accordance with the present amendment, in which claim 50 is amended so as to depend from claim 49, which is among the claims currently under consideration herein.

The examiner further points out in the February 11, 2004 Official Action that this application does not fully comply with the requirements of 37 C.F.R. §§1.821-1.825, because sequence identifiers have not been included in the specification. In accordance with this amendment, sequence identifiers have been added to the specification where appropriate, thus overcoming this ground of objection.

Turning to the substantive aspects of the February 11, 2004 Official Action, claim 52 stands rejected under 35 U.S.C. §112, first paragraph, as the present specification allegedly fails to provide enablement which is adequate for the present claim scope. Applicant disputes the examiner's assertion that additional data is required to support claim 52, which calls for administering to a human the composition

resulting from the method of claim 50. Nonetheless, in the interest of advancing prosecution of this application, claim 52 is being cancelled in accordance with the present amendment.

The only ground of objection or rejection in the February 11, 2004 Official Action that remains to be addressed is the 35 U.S.C. §112, second paragraph rejection of claims 49-52 based on alleged indefiniteness. Specifically, claim 49 is considered vague and indefinite in view of the recitation "immunogenic amino acid". Claim 49 is considered vague and indefinite in view of the recitation "consists of amino acid sequence...and said group, or". Claim 50 is considered vague and indefinite in view of the recitation "one additional component". For the reasons set forth below, this ground of rejection is respectfully traversed.

**Claims 49-52 Fully Comply With The Definiteness
Requirement of 35 U.S.C. §112, Second Paragraph**

The relevant inquiry in determining compliance with the definiteness requirement of 35 U.S.C. §112, second paragraph, is whether the claim in question sets out and circumscribes a particular area with a sufficient degree of precision and particularity, such that the metes and bounds of the claimed invention are reasonably clear. In re Moore, 169 USPQ 236 (CCPA 191).

The definiteness of claim language may not be analyzed in the abstract, but must be considered in light of

the teachings of the prior art and of the particular application disclosure, as it would be interpreted by one having ordinary skill in the art. Id. at 238. To the same effect is Ex parte Cole, 223 USPQ 94 (Bd. App. 1983) (claims are addressed to the person of average skill in a particular art. Compliance with §112 must be adjudged from that perspective, not in a vacuum).

Furthermore, it has long been held that the initial burden of establishing a failure to comply with 35 U.S.C. §112, second paragraph, rests upon the examiner. In rejecting a claim for alleged indefiniteness, therefore, it is incumbent upon the examiner to establish that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claim when read in light of the supporting specification. Ex parte Cordova, 10 USPQ2d 1949, 1952 (PTO B.P.A.I. 1988).

When the appropriate procedural approach is followed in assessing the claim terminology in question, in accordance with the above-noted authorities, it is beyond question that applicant has satisfied the definiteness requirement of §112, second paragraph, with respect to the challenged terminology of claims 49-52.

The examiner is clearly in error in contending that the expression "immunogenic amino acid", in claim 49, is vague and indefinite. When this expression is properly construed in context, one of ordinary skill in the art would have no doubt

as to what constitutes an immunogenic amino acid for purposes of the method of claim 49. The immunogenic amino acid referred to in claim 49 is not just any immunogenic amino acid, but rather one having a "sequence which is found within an amino acid sequence selected from said group", i.e. (i) - (viii). The claim terminology in question does not allow for amino acid substitution within the specified sequences because the claimed peptide must be a fragment of human Fas, but this terminology allows for residues to be removed from the specifically recited sequences, so long as the presence of an immunogenic amino acid sequence is retained. It is well known that antibodies bind epitopes that may be of the order of six (6) amino acids in length and those of ordinary skill in the art could readily determine whether or not removal of amino acids from the recited sequences could be effected while still satisfying the requirements that the peptides be fragments of human Fas and possess an immunogenic character.

The term "immunogenic" is a term of art, the meaning of which is well understood by those skilled in the art, i.e. having the properties of an immunogen or antigen. As such, the term is used to refer to substances which, as the result of coming into contact with appropriate cells, induces an immune response, and which reacts with antibodies generated as a result of such immunogenic response. See the attached definitions from Stedman's Medical Dictionary, 26th Edition at 103, 105 and 855 (1995).

The §112, second paragraph rejection of claim 49, based on the recitation "consists of an amino acid sequence...said group, or" is rendered moot in view of the omission of the objectionable language from claim 49 as now amended. Claim 49 has been further amended to delete a recitation which is considered redundant, in view of the reference to "human antibody molecules" in lines 4 and 5 of claim 49.

The §112, second paragraph rejection of claim 50, is overcome as a result of the present amendment of claim 50 that calls for a pharmaceutically acceptable excipient, carrier, buffer, or stabiliser. Support for this amendment is provided in the present specification at page 32, lines 15-18.

In summary, applicant's position with respect to the rejection of claims 49-52 based on 35 U.S.C. §112, second paragraph is that any person skilled in the art having applicant's disclosure and claims before him or her, would be apprised to a reasonable degree of certainty as the exact subject matter encompassed within claims 49-52. Nothing more is required under 35 U.S.C. §112, second paragraph.

For all of the foregoing reasons, it is clear that in the present case, the examiner has failed to satisfy the PTO's burden of proof with respect to the §112, second paragraph rejection of claims 49-52, as set forth in the February 11, 2004 Official Action. Accordingly, this ground of rejection is untenable and should be withdrawn.

New claims 53 and 54 are included with this amendment. Support for new claim 53 is provided at pages 17-19 of the present specification. Claim 54 parallels claim 50, support for which has already been noted above, but is dependent on claim 53.

Claims 41-48, 51 and 52 have been cancelled in accordance with this amendment.

The claim amendments presented herewith, including the cancellation of claims 51 and 52, should not be construed as indicative of applicant's concurrence or acquiescence in any of the rejections of claims 49-52 set forth in the February 11, 2004 Official Action, or otherwise as an abandonment of applicant's efforts to secure patent protection on the subject matter of claims 51 and 52. To the contrary, applicant vigorously disputes those grounds of rejection. Such arguments as applicant has to advance in rebuttal, however, are being reserved for a continuing application, which is expected to be filed and include, inter alia, the subject matter of cancelled claims 51 and 52.

In view of the present amendment and the foregoing remarks, it is respectfully urged that all of the objections and rejections set forth in the February 11, 2004 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

In the event that a fee is required in connection with the consideration of this amendment and request for

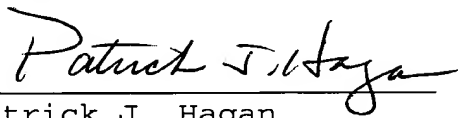
reconsideration, the Commissioner is authorized to debit the account of the undersigned, Deposit Account No. 04-1406. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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Enclosures:

Stedman's Medical Dictionary 26th Edition